DEC 2 7 2000

SECTION 6

6 510(k) SUMMARY

K001499

Prepared May 1, 2000

Product Name:	Computed imaging device
Current Trade Name:	PhorMax Eagle Scanner System
Manufacturer:	PhorMax Corporation 2650 East Bayshore Road Palo Alto, California 94303
Generic Name:	Computed Imaging System
Classification Name:	MQB
Contact Person:	Sheila W. Pickering Ph.D. 2081 Longden Circle Los Altos, California 94024 Telephone/Fax 650 969 6114

6.1 Legally Marketed Predicate Device

The PhorMax Eagle Scanner System (PESS) device is substantially equivalent to the following predicate devices with regard to device features and specifications, as well as intended use.

Table 6.1 Predicate Devices

Reference Number	Sponsor	Predicate Device	510(k) Number
1	Lumisys, Inc.	Lumiscan 135 Phosphor Pate Digitizer	K980809
2	Bayer Corporation, Agfa Division	ADC Compact Agfa Diagnostic Center	K974597
3	Bayer Corporation, Agfa Division	ADC 70	K904519

6.2 Device Description

The system consists of a (1) personal computer, (2) custom software for control, scanning and image formation, (3) an electronic device (scanner) for converting the image to a digital format on the (4) imaging plate enabled by phosphor technology (P/T) which is contained in a (5) cassette-like case. The cassette and plate are designed with a format and size compatible with existing x-ray systems. In use, the imaging plate (enclosed

within the cassette) is exposed to x-rays, using procedures and equipment presently being used on a routine basis for film-based x-ray imaging. The cassette and plate are placed into the scanner and the plate is removed from the cassette, read by the scanner, and returned to the cassette. The scanner converts the image data to a digital format and sends the image data to the PC, where it is converted to a DICOM 3.0 format and saved for subsequent image display.

6.3 Indications for Use

The device is intended to provide diagnostic quality images for aid in physician diagnosis. This is used in the x-ray imaging modality, mainly in Chest, Skeleton and Gastro-intestinal imaging applications.

6.4 Substantial Equivalence

The following tables show the basis for substantial equivalence.

Table 6.2 Substantial Equivalence Comparison

	Predicate Devices		Submission Device	SE
Name	Lumiscan 135 Phosphor Plate Digitizer	ADC Diagnostic Center	PhorMax Eagle Scanner System	
Intended Use	The device is a laser phosphor plate digitizer designed to read recorded patient radiation patterns in the plate and a digitized eraser system to prepare the plate for re-use.	To provide diagnostic quality images for aid in physician diagnosis. This is used in the x-ray imaging modality, mainly in Chest, Skeleton and Gastro-intestinal imaging applications	To provide diagnostic quality images for aid in physician diagnosis. This is used in the x-ray imaging modality, mainly in Chest, Skeleton and Gastro-intestinal imaging applications.	Yes
Intended Users	Radiologists, radiology technicians	Radiologists, radiology technicians	Radiologists, radiology technicians	Yes
Intended site of use	Radiology departments	Radiology departments	Clinical and Radiology sites	Yes
User Interface	User input, manual, graphical	User input, manual, graphical, or cassette	User input, manual, graphical	Yes
Outputs	N / S	N / S	DICOM 3.0 file	Yes
Imaging plates	Agfa	Agfa	Agfa	
Safety Features	N / S	N / S	IEC 60101-1, IEC 60101-2 and ANSI Z136.1	Yes

N/S = not specified in product labeling

6.5 **Performance Data**

The PhorMax Eagle Scanner System was tested for conformance to the technical specifications. Performance testing was based on FDA **"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"** and FDA **"Guidance for the Submission of 510(k)'s for Solid State Imaging Devices"**, August 6, 1999.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2000

PhorMax Corporation
c/o Sheila W. Pickering, Ph.D.
Regulatory Affairs Consultants
2081 Longden Circle
Los Altos, CA 94024

Re: K001499
PhorMax Eagle Scanner System
Dated: November 21, 2000
Received: November 21, 2000
Regulatory class: II
21 CFR 892.1630/Procode: 90 MQB

Dear Dr. Pickering:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): Not applicable K001499

Device Name: PhorMax Eagle Scanner System

Indications For Use:

To provide diagnostic quality images for aid in physician diagnosis. This is used in the x-ray imaging modality, mainly in Chest, Skeleton and Gastro-intestinal imaging applications.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence Of CDRH, Office Of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21CFR 801)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001499